

EXHIBIT 3

**IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF NORTH CAROLINA**

ALLERGAN, INC.,

Plaintiff,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

Civil Action No. 1:14-cv-1028

JURY TRIAL DEMANDED

**DEFENDANT APOTEX'S BRIEF IN SUPPORT OF
ITS RULE 12(B)(6) MOTION TO DISMISS**

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Defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex”) submit this brief in support of their Rule 12(b)(6) Motion to Dismiss.

INTRODUCTION

This case represents Plaintiff Allergan, Inc.’s (“Allergan”) *third* attempt to assert essentially the same patent claims. In 2010, Allergan asserted U.S. Patent No. 7,351,404 (“the ‘404 patent”), which was ultimately held invalid. In 2012 and 2013, Allergan asserted U.S. Patent Nos. 8,263,054 (“the ‘054 patent”), 8,101,161 (“the ‘161 patent”), and 8,038,988 (“the ‘988 patent”), which this Court held invalid, and which Allergan was collaterally estopped from asserting in view of the invalidity of the ‘404 patent. Now, Allergan attempts to assert U.S. Patent No. 8,926,953 (“the ‘953 patent”)—even though the ‘953 patent shares the identical specification as the invalid ‘404, ‘054, ‘161, and ‘988 patents, and asserted claims 8, 23, and 26 (“the asserted claims”) are no different than the invalid claims of those patents.

Rather than requiring Apotex to present its invalidity arguments again for patent claims that are substantially similar to claims already found invalid, the Court should grant Apotex’s Rule 12(b)(6) motion to dismiss. More specifically, for at least the reasons that follow, the invalidity issues as to the asserted claims of the ‘953 patent are identical to those previously litigated, those invalidity issues have been actually determined in prior proceedings, those invalidity determinations were critical and necessary parts of the decisions in those prior proceedings, those prior decisions are final and valid, and Allergan had a full and fair opportunity to litigate those invalidity issues.

As such, Allergan's '953 patent claims in this case fail to state a claim upon which relief may be granted, and they should be dismissed with prejudice.

FACTUAL BACKGROUND

Apotex requests that the Court take judicial notice of the following facts:¹

Federal Circuit Decision

1. On June 10, 2014, the Federal Circuit decided that claim 14 of the '404 patent was invalid for obviousness in view of the Johnstone and Brandt references. *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952 (Fed. Cir. 2014).

Apotex's Motion for Judgment

2. On October 27, 2014, Apotex filed a Rule 12(c) Motion for Judgment on the Pleadings on the ground that that assertion of the '054, '161, and '988 patents was barred by collateral estoppel. (12-cv-00247 (Docs. 103-105); 13-cv-00016 (Docs. 64-66)).

3. On November 20, 2014, Allergan filed a Rule 41(a)(2) Motion to Dismiss seeking dismissal with prejudice of its claims for infringement of the '054, '161, and '988 patents. (12-cv-00247 (Docs. 106-107); 13-cv-00016 (Docs. 67-68)).

4. Also on November 20, 2014, Allergan filed its Response to Apotex's Rule 12(c) Motion for Judgment on the Pleadings. (12-cv-00247 (Doc. 108); 13-cv-00016

¹ See, e.g., *Andrews v. Daw*, 201 F.3d 521, 524 n.1 (4th Cir. 2000) ("[W]hen entertaining a motion to dismiss on the ground of res judicata, a court may take judicial notice of facts from a prior judicial proceeding . . ."). In addition, Apotex incorporates by reference this Court's records in Civil Action Nos. 10-cv-00681, 12-cv-00247, and 13-cv-00016, and respectfully requests that the Court take judicial notice of these records.

(Doc. 69)). There, Allergan conceded Apotex's Rule 12(c) Motion in its entirety. (12-cv-00247 (Doc. 108 at 6) (stating that Allergan may "respond substantively to Apotex's motion at an appropriate time"); 13-cv-00016 (Doc. 69 at 6) (same)).

5. On December 5, 2014, Apotex filed its Reply Brief in Support of its Rule 12(c) Motion for Judgment on the Pleadings. (12-cv-00247 (Doc. 109); 13-cv-00016 (Doc. 70)). In this Reply, Apotex stated, "Allergan has utterly failed to substantively respond to Apotex's Rule 12(c) motion." (12-cv-00247 (Doc. 109 at 4); 13-cv-00016 (Doc. 70 at 4)).

6. On December 15, 2014, Apotex filed its Opposition to Allergan's Rule 41(a)(2) Motion to Dismiss. (12-cv-00247 (Doc. 110); 13-cv-00016 (Doc. 71)). In this Reply, Apotex repeated that "Allergan has utterly failed to substantively respond to Apotex's Rule 12(c) motion." (12-cv-00247 (Doc. 110 at 5); 13-cv-00016 (Doc. 71 at 5)).

7. Over two weeks later, on January 2, 2015, Allergan filed its Reply in Support of its Rule 41(a)(2) Motion to Dismiss. (12-cv-00247 (Doc. 112); 13-cv-00016 (Doc. 75)). In this Reply, Allergan did not respond substantively to Apotex's Rule 12(c) Motion. (*See generally* 12-cv-00247 (Doc. 112); 13-cv-00016 (Doc. 75)).

Final Judgments

8. On January 14, 2015, this Court entered its Final Judgment that claim 14 of the '404 patent is "declared to be invalid as obvious under 35 U.S.C. § 103." (10-cv-00681 (Doc. 250)) ("Final Judgment I").

9. Also on January 14, 2015, this Court entered its Final Judgment that the “‘988, ‘161, and ‘054 patents are declared and adjudged invalid as obvious under 35 U.S.C. § 103” and that “Allergan is collaterally estopped from asserting the ‘988, ‘161, and ‘054 patents against Apotex or contesting the invalidity of those patents.” (12-cv-00247 (Doc. 114); 13-cv-00016 (Doc. 77)) (“Final Judgment II”).

Full and Fair Opportunity

10. At least between **(A)** the date that Apotex filed its Rule 12(c) Motion for Judgment in Civil Action Nos. 12-cv-00247 and 13-cv-00016 (October 27, 2014); and **(B)** the date this Court entered Final Judgment I and Final Judgment II (January 14, 2015), Allergan had a full and fair opportunity to provide this Court with any substantive opposition to Apotex’s Rule 12(c) Motion for Judgment on the Pleadings. Yet Allergan provided no substantive opposition. *See* Docket Report: Civil Action No. 12-cv-00247 (attached as Exhibit B to the *Declaration of Luke T. Shannon, Esq.*, filed on June 22, 2015 (“*Shannon Dec.*”)); Docket Report: Civil Action No. 13-cv-00016 (Exhibit C to *Shannon Dec.*).

The Invalidated Claims

11. As stated above, this Court entered judgment that claim 14 of the ‘404 patent is invalid.

12. Claim 14 of the ‘404 patent depends from claim 13, which depends from claim 1.

13. Claim 1 of the ‘404 patent reads: “A method for stimulating hair growth in a mammalian species comprising the application to mammalian skin of an effective amount of a [compound selected from a group reflecting a chemical structure Allergan alleged to include bimatoprost].” (10-cv-00681 (Doc. 1-1 at claim 1)).

14. Claim 13 reads: “The method of claim 1 wherein hair growth is eye lashes.” (10-cv-00681 (Doc. 1-1 at claim 13)).

15. Claim 14 reads: “The method of claim 13 wherein said compound is bimatoprost.” (10-cv-00681 (Doc. 1-1 at claim 14)).

16. Claim 14 of the ‘404 patent thus can be rewritten, if incorporating the dependent claim elements within the claim 1 framework, as: “A method for stimulating [eyelash] growth² in a mammalian species comprising the application to mammalian skin of an effective amount of [bimatoprost].”

17. This Court invalidated the relevant claims of the ‘054, ‘161, and ‘988 patents. In particular, this Court invalidated claims 1-17 of the ‘054 patent, 1-24 of the ‘161 patent, and 1-3, 6 and 10-11 of the ‘988 patent. (*See* 12-cv-00247 (Doc. 104 at 7 n.4); 13-cv-00016 (Doc. 65 at 7 n.4); *see also* 12-cv-00247 (Doc. 114 at 3); 13-cv-00016 (Doc. 77 at 3)).

² The Court construed this “method for stimulating hair growth” as a “method of converting vellus or intermediate hair to growth as terminal hair, increasing the rate of hair growth, increasing the number of anagen hairs, decreasing the number of telogen hairs, preventing atrophy of hair follicles, stimulating the growth of vellus hair to terminal hair on the skin, or increasing the length, number or thickness of hair.” (10-cv-00681 (Doc. 180 at 3)).

18. These claims of the ‘054, ‘161, and ‘988 patents appear in the record at Civil Action No. 13-cv-00016 (Doc. 1-1) (‘054 patent), Civil Action No. 12-cv-00247 (Doc. 42-1) (‘161 patent), and Civil Action No. 12-cv-00247 (Doc. 6-1) (‘988 patent).

The New Patent

19. In the present action, Allergan filed a Complaint on December 9, 2014, asserting that Apotex infringes U.S. Patent No. 8,906,962 (“the ‘962 patent”). (14-cv-01028 (Doc. 1)).

20. On January 9, 2015, Allergan filed its First Amended Complaint adding claims that Apotex infringes the ‘953 patent. (14-cv-01028 (Doc. 11)).

21. After the Court granted Allergan leave, (14-cv-01028 (Doc. 31)), Allergan filed its Second Amended Complaint on May 22, 2015. (14-cv-01028 (Doc. 32)).

22. Allergan’s second amended Complaint alleges that Apotex infringes claims 8, 23, and 26 of the ‘953 patent, and does not allege that Apotex infringes the ‘962 patent. (*See generally* 14-cv-01028 (Doc. 32)).

23. The claims of the ‘953 patent appear at 14-cv-01028 (Doc. 11-2).

ARGUMENT

I. Legal Standard.

This Court is well-versed in the Rule 12(b)(6) dismissal standard. *See, e.g., City of Greensboro v. Labrie Enviroquip Grp.*, No. 1-14-cv-683, 2015 WL 300461, at *2 (M.D.N.C. Jan. 22, 2015). The question of collateral estoppel may be decided on a Rule 12(b)(6) motion to dismiss. *Brooks v. Arthur*, 626 F.3d 194, 200 (4th Cir. 2010);

Andrews, 201 F.3d at 524 n.1 (“This Court has previously upheld the assertion of res judicata in a motion to dismiss.”). As noted above, this Court “may take judicial notice of facts from a prior judicial proceeding when the res judicata defense raises no disputed issue of fact.” *Andrews*, 201 F.3d at 524 n.1.

Collateral estoppel precludes “relitigation” where:

(1) the issue sought to be precluded is identical to one previously litigated; (2) the issue must have been actually determined in the prior proceeding; (3) determination of the issue must have been a critical and necessary part of the decision in the prior proceeding; (4) the prior judgment must be final and valid; and (5) the party against whom the estoppel is asserted must have had a full and fair opportunity to litigate the issue in the previous forum.

Sedlack v. Braswell Servs. Grp., Inc., 134 F.3d 219, 224 (4th Cir. 1998). In a patent infringement context, the application of collateral estoppel is not limited to “patent claims that are identical.” *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013). “Rather, it is the identity of the *issues* that were litigated that determines whether collateral estoppel should apply.” *Id.* (original emphasis).

“If the differences between the unadjudicated patent claims and the adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies.” *Id.* at 1342. The mere use of different words in the unadjudicated claims does not necessarily create a new issue of invalidity. *Id.* at 1343. Instead, the primary question is whether the asserted claims are “substantially similar” to the invalidated claims. *Id.* at 1342. In other words, any differences in the asserted claims must be “patentably significant” in a way that “changes the invalidity analysis.” *Id.* at 1343.

II. The Asserted Claims of the ‘953 Patent Are Equally Invalid.

The following analysis tracks the five *Sedlack* factors identified above.

A. The issues are identical.

This Court already has decided that the relevant claims of the ‘054, ‘161, and ‘988 patents are substantially similar to claim 14 of the ‘404 patent. The ‘953 patent presents the identical invalidity issue. The asserted claims of the ‘953 patent are substantially the same as—or *at least* substantially similar to—invalidated claims of the ‘404, ‘054, ‘161, and ‘988 patents. The following charts use three colors (yellow, blue, and green) to compare the elements of several invalidated claims to the corresponding elements of the asserted claims of the ‘953 patent.³ As is easily seen, the ‘953 patent does no more than rearrange elements presented in claims already held invalid.

The asserted claims of the ‘953 patent and the claims from which each depends appear as follows:

‘953 Patent (claim 8)	‘953 Patent (claim 23)	‘953 Patent (claim 26)
1. A method of enhancing the growth of one selected from the group consisting of eyelashes, eyebrows and scalp hair, wherein the method comprises topical	10. A method for use in enhancing the growth of one selected from the group consisting of eyelashes, eyebrows and scalp hair, comprising topically	1. A method of enhancing the growth of one selected from the group consisting of eyelashes, eyebrows and scalp hair, wherein the method comprises topical

³ Although Apotex herein compares the asserted claims of the ‘953 to several claims already held invalid in the ‘404 and ‘054 patents, these ‘054 patent claims are merely representative of the substantial similarities of the ‘953 patent asserted claims with claims already held invalid. The asserted claims of the ‘953 patent are substantially similar to additional claims of the ‘054, ‘161 and/or ‘988 patents already held invalid, and Apotex reserves the right to argue that the asserted claims of the ‘953 patent are substantially similar to any claim already held invalid in the ‘404, ‘054, ‘161, or ‘988 patents.

<p>application of a bimatoprost composition.</p> <p>2. The method of claim 1, wherein the composition is a bimatoprost solution.</p> <p>3. The method of claim 2, wherein the composition is a 0.03% w/v bimatoprost solution.</p> <p>5. The method of claim 3, wherein the method is useful for the treatment of hypotrichosis of the eyelashes.</p> <p>8. The method of claim 5, wherein the composition increases the length, thickness and darkness of eyelashes.</p>	<p>applying at least once a day a composition comprising bimatoprost.</p> <p>14. The method of claim 10, wherein the composition is a 0.03% w/v bimatoprost solution and is useful for treating hypotrichosis of the eyelashes by increasing one attribute selected from the group consisting of length, thickness and darkness of eyelashes.</p> <p>23. The method of claim 14, wherein the attribute is darkness.</p>	<p>application of a bimatoprost composition.</p> <p>2. The method of claim 1, wherein the composition is a bimatoprost solution.</p> <p>3. The method of claim 2, wherein the composition is a 0.03% w/v bimatoprost solution.</p> <p>5. The method of claim 3, wherein the method is useful for the treatment of hypotrichosis of the eyelashes.</p> <p>6. The method of claim 5, wherein the composition increases one attribute selected from the group consisting of length, thickness and darkness of eyelashes.</p> <p>26. The method of claim 6, wherein the attribute is darkness.</p>
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Claim 14 of the '404 patent and claims 1, 2, 3 and 5 of the '054 patent, all of which have been held invalid, appear as follows:

'404 Patent	'054 Patent
<p>1. A method for stimulating hair growth in a mammalian species comprising the application to mammalian skin of an effective amount of a [compound selected from a group that Allergan alleged includes bimatoprost].</p> <p>13. The method of claim 1 wherein hair</p>	<p>1. A method of increasing eyelash growth in a human including length, thickness and darkness of the eyelashes, the method comprising administering bimatoprost to an eyelid margin of the human.</p> <p>2. The method of claim 1 wherein the bimatoprost is administered in the form of a liquid composition containing about 0.03%</p>

growth is eye lashes.	w/v bimatoprost.
14. The method of claim 13 wherein said compound is bimatoprost.	3. The method of claim 1 wherein bimatoprost is administered to the upper eyelid margin at least once a day.
	5. The method of claim 1 wherein the patient is suffering from eyelash loss.

These claims all contain the same three elements: yellow highlighting shows the “method for stimulating eyelash growth” element; blue highlighting shows the “topical [*i.e.*, skin] application” element; and green highlighting shows the “use of bimatoprost” element. A side-by-side comparison of each element illustrates the substantial similarity of the ‘953 patent claims and invalid claims.

The “method for stimulating hair growth” element is shown below:

<i>‘953 Patent</i>	<i>‘404 Patent (claim 14)</i>	<i>‘054 Patent (claim 5)</i>
<p>Claim 8:</p> <p>A method of enhancing the growth of one selected from the group consisting of eyelashes, eyebrows and scalp hair...wherein the method is useful for the treatment of hypotrichosis of the eyelashes...[and] wherein the composition increases the length, thickness and darkness of eyelashes.</p> <p>Claim 23:</p> <p>A method for use in enhancing the growth of one selected from the group consisting of eyelashes, eyebrows and scalp hair...[wherein the required composition is] useful for treating hypotrichosis of the eyelashes by increasing one attribute selected from the group consisting of length, thickness</p>	<p>A method for stimulating hair growth...wherein hair growth is eye lashes.</p>	<p>A method of increasing eyelash growth in a human including length, thickness and darkness of the eyelashes...wherein the patient is suffering from eyelash loss.</p>

<p>and darkness of eyelashes...[and] wherein the attribute is darkness.</p> <p>Claim 26:</p> <p>A method of enhancing the growth of one selected from the group consisting of eyelashes, eyebrows and scalp hair...wherein the method is useful for the treatment of hypotrichosis of the eyelashes...[and] wherein the composition increases one attribute selected from the group consisting of length, thickness and darkness of eyelashes...[and] wherein the attribute is darkness.</p>		
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This element in the asserted claims of the ‘953 patent is substantially similar to its counterpart in claim 14 of the ‘404 patent and claim 5 of the ‘054 patent. Any distinctions between the language Allergan chose to use in the asserted claims of the ‘953 patent would be contrived, particularly given Allergan’s prior claim construction and infringement positions. (*See* 10-cv-00681 (Doc. 180 at 3)).

Nor does the asserted claims’ use of the word “darkness” change the analysis. Several ‘054 patent claims explicitly require “darkness.” But even apart from the ‘054 patent, the Court’s claim construction forecloses any distinction from the use of “darkness.” The Court construed “a method for stimulating hair growth” as

a method of converting vellus or intermediate hair to growth as terminal hair, increasing the rate of hair growth, increasing the number of anagen hairs, decreasing the number of telogen hairs, preventing atrophy of hair follicles, stimulating the growth of vellus to terminal hair on the skin, or increasing the length, number or thickness of hair.

(10-cv-00681 (Doc. 180 at 3)). The ‘404 and ‘953 patents provide, “For the purposes of the present invention, it is necessary to consider various types of hair, including, terminal hairs and vellus hairs. . . . Terminal hairs are coarse, pigmented, long hairs. . . . Vellus hairs, on the other hand, are fine, thin, non-pigmented short hairs.” (14-cv-01028 (Doc. 11-2, the ‘953 patent at col. 1, ll. 44-50; Doc. 26-1, the ‘404 patent at col. 1, ll. 32-38)). Because the Court’s construction of “stimulating hair growth” includes conversion from vellus hair to terminal hair, “stimulating hair growth” includes increased pigmentation, which Allergan has equated with “darkening.” (*See* 14-cv-01028 (Doc. 25 at 6)).

The ‘953 patent treats “darkness” as just an indicator of hair growth. “Darkness” appears only in the asserted claims, and the ‘953 patent lists “increased pigmentation of the lashes” alongside other lash characteristics and states, “The conclusion that hair growth is stimulated by bimatoprost” is “based on multiple parameters of hair appearance.” (14-cv-01028 (Doc. 11-2, the ‘953 patent at col. 7, ll. 33-48)).

The “topical application” element is substantially similar in the ‘953 patent and claim 14 of the ‘404 patent and claim 3 of the ‘054 patent:

‘953 Patent	‘404 Patent (claim 14)	‘054 Patent (claim 3)
Claim 8 topical application Claim 23 topically applying at least once a day Claim 26 topical application	application to mammalian skin	administering bimatoprost to...the upper eyelid margin at least once a day

Even ‘953 patent claim 8’s once-daily application requirement is pulled directly from ‘054 patent claim 3.

Finally, the “use of bimatoprost” element also is substantially similar:

<i>‘953 Patent</i>	<i>‘404 Patent (claim 14)</i>	<i>‘054 Patent (claim 2)</i>
<p>Claim 8</p> <p>of a bimatoprost composition...wherein the composition is a bimatoprost solution...[and] wherein the composition is a 0.03% w/v bimatoprost solution</p> <p>Claim 23</p> <p>a composition comprising bimatoprost...wherein the composition is a 0.03% w/v bimatoprost solution</p> <p>Claim 26</p> <p>of a bimatoprost composition...wherein the composition is a bimatoprost solution...[and] wherein the composition is a 0.03% w/v bimatoprost solution</p>	<p>wherein said compound is bimatoprost</p>	<p>wherein the bimatoprost is administered in the form of a liquid composition containing about 0.03% w/v bimatoprost</p>

Indeed, even the “0.03% w/v” concentration requirement of the ‘953 patent asserted claims is found in, for example, ‘054 patent claim 2.

Simply put, the ‘953 patent is a classic example of using slightly different language to claim the same thing. *See Ohio Willow Wood*, 735 F.3d at 1342 (“As reflected in the claim language above, these patents use slightly different language to describe substantially the same invention.”). In *Ohio Willow Wood*, the Federal Circuit found the asserted patent to be substantially similar to a patent that had already been found invalid. *Id.* In so finding, the Federal Circuit recognized the differences in claim language, but nonetheless viewed the claims as substantially similar:

For example, where the [asserted] ‘237 patent recites a “tube sock-shaped covering,” an “amputation stump being a residual limb,” and a “fabric in the shape of a tube sock,” the [previously adjudicated invalid] ‘182 patent analogously recites the same claim scope in the form of a “cushion liner for enclosing an amputation stump, said liner comprising a fabric covering having an open end for introduction of said stump and a closed end opposite said open end.”

Id. at 1342-43.

Here, if anything, the language of each claim of the ‘953 patent is even closer to one or more claims already held invalid than were the claims at issue in *Ohio Willow Wood*. Each asserted claim of the ‘953 patent can be easily aligned with both invalid claim 14 of the ‘404 patent and invalid claims of the ‘054, ‘161, and/or ‘988 patents: each claims a method for stimulating eyelash growth, using topical (*i.e.*, skin) application of bimatoprost. The various words and phrases Allergan spread across various patents does not, in and of itself, “create a new issue of invalidity.” *See id.* at 1343.

The inescapable conclusion is that the ‘953 patent is Allergan’s latest attempt to advance arguments already rejected by the Federal Circuit and this Court. Apotex already has demonstrated convincingly that the subject matter claimed by the ‘953 patent

is obvious over the prior art; requiring Apotex to do so yet again would serve no purpose but to waste the Court's and the parties' time and resources.

Because the asserted claims of the '953 patent describe substantially the same purported invention as the many related patent claims already held invalid, the invalidity issues surrounding the claims of the '953 patent are identical to those already addressed with respect to claim 14 of the '404 patent, as well as the claims of the '054, '161, and/or '988 patents. Thus, the first *Sedlack* factor is satisfied.

B. Invalidity was actually determined in the previous actions.

As set forth above, a central issue in the Federal Circuit's opinion was that claim 14 of the '404 patent is invalid as obvious over the prior art. *Allergan*, 754 F.3d at 970. Moreover, in granting Apotex's Rule 12(c) Motion for Judgment, this Court specifically found and adjudged the '054, '161, and '988 patents invalid. (12-cv-00247 (Doc. 114); 13-cv-00016 (Doc. 77)). The Federal Circuit and this Court were not simply addressing peripheral or underlying issues, but instead squarely addressed the validity of claims identical to the asserted claims of the '953 patent. Thus, the second *Sedlack* factor is met.

C. Invalidity was critical and necessary to the previous decisions.

Invalidity was critical and necessary to both the Federal Circuit's and this Court's prior decisions. Because invalidity issues were the sole issues that led to the termination of Allergan's prior actions, *see generally Allergan*, 754 F.3d 952; (12-cv-00247 (Doc. 114); 13-cv-00016 (Doc. 77)), invalidity was critical and necessary to both the Federal Circuit's decision and this Court's dismissal. Thus, the third *Sedlack* factor is met.

D. This Court's previous judgments are final and valid.

As noted above, on June 10, 2014, the Federal Circuit found that the '404 patent was obvious over the prior art. *Allergan*, 754 F.3d at 970. If there were any doubt, this Court, on January 14, 2015, entered a Final Judgment vacating its January 25, 2013 Judgment and April 23, 2013 Permanent Injunction and Final Judgment, and declared claim 14 of the '404 patent invalid as obvious. (10-cv-00681 (Doc. 250)).

The Court's findings that the claims of the '054, '161, and '988 patents are invalid are also final. On January 14, 2015, the Court issued its Final Judgment, which entered judgment in favor of Apotex and against Allergan "on all of Apotex's counterclaims alleging invalidity" of the '054, '161, and '988 patents. (12-cv-00247 (Doc. 114 at 2-3); (13-cv-00016 (Doc. 77 at 2-3)). The Court also "declared and adjudged [the '988, '161, and '054 patents] invalid as obvious under 35 U.S.C. § 103." (12-cv-00247 (Doc. 114 at 3); (13-cv-00016 (Doc. 77 at 3)). The fourth *Sedlack* factor is therefore met.

E. Allergan had a full and fair opportunity to litigate.

Allergan had a full and fair opportunity to litigate the invalidity of the '404, '054, '161, and '988 patent claims. As to the '404 patent, Allergan litigated the issue of validity of the '404 patent through trial and appeal. It presented evidence and had ample opportunity to support its arguments at trial and on appeal before the Federal Circuit.

As to the '054, '161, '988 patents, Allergan likewise had ample opportunity to try to relitigate the invalidity issue; the fact that Allergan repeatedly elected to forego any substantive opposition does not negate its many opportunities. In presenting its Rule

12(c) Motion, Apotex explicitly invited Allergan to present argument as to how any differences between the claims of the ‘054, ‘161, and ‘988 patents on the one hand and claim 14 of the ‘404 patent on the other hand are somehow “patentably significant.” (E.g., 12-cv-00247 (Doc. 104 at 9); 13-cv-00016 (Doc. 65 at 9)). Allergan brought forth no substantive opposition to Apotex’s arguments. Nor did Allergan raise any substantive opposition to Apotex’s arguments in Allergan’s Reply in support of its Reply in Support of its Rule 41(a)(2) Motion to Dismiss. Nor has Allergan in any way moved the Court to reconsider or otherwise challenged the Court’s entry of the Final Judgment declaring and adjudicating the claims of the ‘054, ‘161, and ‘988 patents invalid. Stated simply, Allergan had more than a full and fair opportunity to argue that the ‘054, ‘161, and ‘988 patents were valid. Therefore, the final *Sedlack* factor is met.

* * *

Because the *Sedlack* factors are all met, Allergan should be precluded from asserting the asserted claims of the ‘953 patent against Apotex.

CONCLUSION

Allergan’s “new” claim and cause of action that Apotex infringes the asserted claims of the ‘953 patent is really the same claim the Federal Circuit and this Court have heard before and which has been roundly rejected. The claims of the ‘953 patent are not new, and Allergan has had ample opportunity to litigate the validity of these claims. Allergan lost. It should not now be rewarded with an opportunity relitigate this issue, which has been conclusively decided.

Instead, Allergan should be collaterally estopped from asserting the '953 patent against Apotex, and its claims should be dismissed with prejudice.

Respectfully Submitted,

Dated: June 22, 2015

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CERTIFICATE OF SERVICE

I hereby certify that I have this day electronically filed the foregoing APOTEX'S BRIEF IN SUPPORT OF ITS RULE 12(b)(6) MOTION TO DISMISS and accompanying documents with the Clerk of Court using the CM/ECF system, which will send notification to all parties.

This the 22nd day of June, 2015.

/s/Gregory G. Holland

Gregory G. Holland
N.C. State Bar No. 19069